

REMARKS

In the non-final office action that was mailed December 11, 2007, the Examiner allowed claim 38, objected to claim 19 as being dependent upon a rejected base claim, and rejected claims 1-4, 7-18, 20-24, 26, 29-37, and 39. Applicants have amended claims 1, 26, 29, 32 and 37 to more particularly define the subject matter sought to be patented, and have added new claim 40. The amendments add no new matter. Applicants have canceled without prejudice claims 22-23, 30-31, and 39. Claims 1-4, 7-21, 24, 26, 29, 32-38, and 40 are pending, with claim 35 being withdrawn as drawn to a non-elected species. Applicants request reconsideration in view of the amendments above and the following remarks.

Response to Claim Rejections

Claim 30

The Examiner rejected claim 30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Separately, based on the Examiner's contentions at page 8 of the Office Action, Applicants believe that the Examiner intended to reject claim 30, rather than claim 26, as being unpatentable over Brockway '191 in view of U.S. Patent No. 5,135,501 to Cameron ("Cameron"). See Office Action page 8.

Applicants have canceled claim 30 without prejudice.

Claims 31-34, 39, and new claim 40

The Examiner rejected claims 31 and 39 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,353,800 to Pohndorf ("Pohndorf"), and rejected claims 32-34 under 35 U.S.C. § 103(a) as unpatentable over Pohndorf. Separately, the Examiner rejected claim 34 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Applicants have canceled claims 31 and 39 without prejudice, and have rewritten claim 32 in independent form. Applicants have added new claim 40, which is directed to a method of producing an implantable pressure sensing device. The amendments add no new matter and are fully supported by the specification as originally filed (e.g., at original claims 31-34, and paragraphs [0077]-[0086]).

Claim 32 is patentable over Pohndorf because Pohndorf does not disclose or suggest an implantable pressure sensing device including a pressure transmission catheter with a pressure transmission fluid and a barrier to retain the fluid, wherein the pressure transmission catheter containing the pressure transmission fluid and barrier collectively act as a low-pass filter for frequencies above 10 Hz. Neither is claim 32 obvious in view of Pohndorf, because Pohndorf lacks any teaching or suggestion that design features or parameters, such as the claimed pressure transmission fluid and barrier, may be selected to achieve a device with desired filtering properties. Pohndorf determines that a flat frequency response in the range of zero to twenty hertz is a property of one device, and states that this offers "acceptable" performance, but does not disclose or suggest a pressure transmission catheter with pressure transmission fluid and a barrier that collectively act as a low-pass filter for frequencies above 10 Hz. In fact, Pohndorf discloses that "[i]deally, . . . , it would be preferable . . . to have a flat frequency response from at least zero to one-hundred hertz," a frequency ten times higher than the frequency recited in claim 32. For at least these reasons, claim 32 is patentable over Pohndorf, as are dependent claims 33-34, and Applicants request removal of the rejections to these claims.

New claim 40 is patentable over the references of record because none of the references discloses or suggests selecting at least one of the claimed device properties to achieve an appropriate low-pass filter half-power frequency for the device.

With regard to the enablement rejection of claim 34, Applicants respectfully traverse, and submit that the specification as originally filed provides sufficient enablement support to satisfy 35 U.S.C. § 112, first paragraph. Claim 34 is directed to an implantable pressure sensing device, not to a method of using the device, and Applicants' original specification fully enables a person having ordinary skill in the art to make and use the device. As disclosed at paragraph [0077], "certain properties of the PTC 34 and the medium employed within the PTC 34 to transfer the pressure signal may be designed to filter out higher frequency components of the pressure signal to thereby reduce frequency response." See paragraph [0077]. Paragraph [0078] continues, "by way of example, not limitation, reducing the lumen diameter of the PTC 34, increasing the viscosity of the fluid in the lumen of the PTC 34, increasing the length of the portion of the PTC

34 containing the gel, filling the whole length of the PTC with gel increasing the viscosity of the gel, increasing the length of the PTC 34, and increasing the compliance of the PTC 34 and/or the pressure sensor.” See paragraph [0078]. Additionally, paragraph [0081] discloses that “depending on the clinical application, the PTC 34 may filter out frequencies above 50 Hz, 10 Hz, 5 Hz, or 1 Hz.” See paragraph [0081]. As such, a person having ordinary skill in the art reading Applicants’ specification would have appreciated that the presently claimed device to filter out frequencies above 1 Hz can be used to assess mean pressure, or trends in pressure over time. Applicants request that the Examiner remove the enablement rejection of claim 34.

Claims 1-4, 7-21, and 36

The Examiner rejected claims 1-4, 9, 13, 15, 21, and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,846,191 to Brockway et al. (“Brockway ‘191”) in view of U.S. Patent No. 6,592,656 to Twardowski (“Twardowski”). Of these, claim 1 is independent. The Examiner also rejected claims 7-8, 10-12, 14, 16-18, and 20, which depend either directly or indirectly from claim 1, under U.S.C. § 103(a) as being unpatentable over various references.

Applicants have amended claim 1 to recite that the surface modification on an outside surface of “a distal portion of” the catheter that promotes tissue in-growth “at a blood interface.” The amendment adds no new matter, and support can be found at least in paragraph [0039] of the original specification.

Twardowski discloses perfusion catheters for insertion into either the jugular or left subclavian veins. See Fig. 1, col. 1, lns. 5-8. The catheters are not fully implanted within the body of the patient, but rather exit the body through the skin. See Fig. 1. Twardowski discloses an outer cuff located close (1-3 cm) to the skin exit, and an inner cuff located 2-6 cm from the outer cuff. See col. 13, ln. 49 to col. 14, ln. 37. The cuffs provide for tissue ingrowth “in the catheter tunnel,” see col. 13, lns. 49-53, and as shown in FIG. 1 are located between the skin exit point and the vein entry point.

Claim 1 is patentable over the references of record because the references fail to disclose or suggest an implantable pressure sensing device that includes, *inter alia*, a pressure

transmission catheter with a surface modification on an outside surface of a distal portion of the catheter, wherein the surface modification promotes tissue in-growth at a blood interface. By promoting tissue in-growth "at a blood interface," the surface modification may permit healing at an injury site into the vessel or cardiac chamber – in particular, at a site where the catheter enters a blood vessel or cardiac chamber. This can aid in healing in the days or weeks after implantation to prevent blood leakage from the vessel or chamber, for example, or to prevent formation of unstable thrombus bundles, which may later detach with adverse consequences for the patient. For example, motion of the heart muscle relative to the catheter may lead to unstable thrombus growth between the heart wall (or blood vessel in peripheral vascular applications) and the catheter, which can lead to a dangerous cardiac event or stroke should the thrombus become dislodged. The surface modification described in claim 1 can be used to promote faster healing at the vessel or chamber entrance site for pressure measurement, as tissue may grow into the material and stabilize the injury site. These advantages are not contemplated by Twardowski, which is focused on an entirely different issue. Namely, Twardowski is concerned with stabilizing the catheter in a catheter tunnel near the skin entry point, away from the blood interface, so that jostling of the catheter external to the body does not upset the portion of the catheter within the catheter tunnel. For at least these reasons, amended claim 1, as well as dependent claims 2-4, 7-18, 20-21, and 36 are patentable over the references of record, and Applicants request removal of the rejections to these claims.

Claim 37

The Examiner rejected claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Brockway '191 in view of Twardowski and further in view of U.S. Patent No. 5,520,664 to Bricault et al. ("Bricault").

Applicants have amended claim 37 in similar fashion to the claim 1 amendments, described above. The amendment adds no new matter, and is fully supported by the original specification.

Claim 37 is patentable over a combination of Brockway '191 and Twardowski for at least the reasons discussed above with reference to claim 1, and Bricault fails to cure the deficiencies of Brockway '191 and Twardowski. As such, claim 37 is patentable over the references of record, and Applicants request removal of the rejection to this claim.

Claims 22-24

The Examiner rejected claims 22-24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,160,448 to Jackson ("Jackson") in view of Brockway '191. Applicants have canceled claims 22-23 without prejudice.

Claim 24 is directed to an implantable pressure sensing device that includes, among other things, a pressure transmission catheter that comprises a tube, where the distal end of the catheter is closed by an integral extension of the tube. One example of this can be seen in the original specification at Fig. 5S, and described at paragraph [0066].

Jackson discloses a cannula filled with a liquid, and includes at its distal end a balloon 12. *See* Fig. 5; col. 2, lns. 10-14. The Examiner contended that the balloon was an integral extension of the catheter. This is not correct. Jackson discloses that "the balloon material is secured about the periphery of the end of the catheter," *see* col. 2, lines 28-29, and as such the balloon is not an integral extension of the tube. Also, at no point does Jackson disclose or suggest closing the catheter by an integral extension of the catheter tube.

For at least these reasons, claim 24 is patentable over the references of record, and Applicants request the removal of the rejection to this claim.

Claim 26

The Examiner rejected claim 26 under 35 U.S.C. § 103(a) as being unpatentable over Brockway '191 in view of Twardowski and further in view of U.S. Patent No. 5,480,711 to Ruefer ("Ruefer"). Applicants have amended claim 26 in similar fashion to the claim 1 amendments, described above. The amendment adds no new matter, and is fully supported by the original specification. The Examiner also rejected claim 26 as being unpatentable over Brockway '191 in view of U.S. Patent No. 5,135,501 to Cameron ("Cameron") at page 8 of the Office Action. As described above, Applicants believe that the Examiner intended this rejection

to apply to claim 30, not claim 26. Regardless, claim 26 is patentable over Brockway '191 and Cameron for at least the reasons discussed above with reference to claim 1.

Claim 26 is also patentable over a combination of Brockway '191 and Twardowski for at least the reasons discussed above with reference to claim 1, and Ruefer fails to cure the deficiencies of Brockway '191 and Twardowski. As such, claim 26 is patentable over the references of record, and Applicants request removal of the rejection to this claim.

Claim 29

Claim 29 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson in view of U.S. Patent No. 4,405,313 to Sisley et al. ("Sisley").

Applicants have amended claim 29 in similar fashion to the claim 1 amendments, described above. The amendment adds no new matter, and is fully supported by the original specification.

Claim 29 is patentable over the references of record because none of the references, whether alone or in combination, disclose or suggest an implantable pressure sensing device, that includes, *inter alia*, a pressure transmission catheter, wherein at least a distal portion of the catheter includes a modification to the outer surface of the catheter including an outer layer of material that comprises polyester fabric to at least one of, at a blood interface site, promote tissue in-growth, prevent migration of infectious contaminants, improve a seal between the catheter and surrounding tissue, improve anchoring between the catheter and surrounding tissue, and improve endothelialization.

Sisley discloses a cuff that, like the cuffs disclosed in Twardowski, are not located at a blood interface. Indeed, Sisley discloses that the cuff is "located substantially midway between the point of entry to the skin and point of entry to the vessel to promote tissue in-growth which will fix the catheter within the patient." *See* Abstract. As with Twardowski, this is very different from the device recited in Applicants' claim. For at least these reasons, claim 29 is patentable over the references of record, and Applicants request withdrawal of the rejection to this claim.

CONCLUSION

Applicants submit that each of claims 1-4, 7-21, 24, 26, 29, 32-38, and 40 is in condition for allowance, and request that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, objection, issue or comment does not signify agreement with or concession of that rejection, objection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply the required fee of \$525 for Petition for Three-Month Extension of Time any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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